K113500

DEC - 9 2011

510(k) Summary

(per 21 CFR 807.92(c))

1. **Applicant**

US Medical Innovations, LLC
2940 Winter Lake Road
Lakeland, Florida 33803

Contact Person:
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Date Prepared: October 11, 2011

2. **Device Name and Classification**

Trade Name(s): Canady Vieira Hybrid Plasma™ Scalpel, AW-422552

Common Name: Electrosurgical, cutting & coagulation & accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Regulation: 21 CFR 878.4400
Panel: General, Restorative, and Neurological Devices
Product Code: GEI
Class: II

3. **Predicate Devices**

The Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K955020	Telescoping Pen Evac ABC	I.C. Medical, Inc.
K964636	Force Argon II Argon Enhanced	Valley Lab

4. **Description of the Device**

The Canady Vieira Hybrid Plasma™ Scalpel is an accessory multi-functional electrosurgical handpiece used for open surgical procedures where monopolar radio frequency electrosurgical handpieces (cutting, coagulation) is normally used. The handpiece uses radio frequency (RF)

monopolar electrosurgical current to cut or coagulate biological tissue. The handpiece can also combine argon gas with radio frequency monopolar cut or coagulation currents to produce a hybrid plasma cut, or argon plasma coagulation.

The handpiece consists of three major components: Handle, Telescoping Nozzle, and Electrode. The insulated handle encases the radio frequency (RF) current and gas tubing for controlling the flow of argon gas and activation of RF current for the device. RF current is activated by two push buttons yellow (standard CUT mode) and blue (standard COAG mode) which are top of the handle. Argon gas is delivered via the handle by activating a third push button (purple) which is also on top of the handle. The electrode tip has 4 modes of operation and as shown in the below table, this words appear depending on the mode of operation that is necessary.

Table 5-1

Canady Vieira Hybrid Plasma™ Scalpel Mode	Operation being performed
CUT	Cuts Tissue
COAG	Coagulates Tissue
ARGON PLASMA COAG	Coagulates Tissue
CANADY VIEIRA HYBRID PLASMA CUT	Cuts Tissue

Depending on the RF current mode (CUT or COAG), the handpiece can function in the following argon modes: HYBRID PLASMA CUT – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the CUT mode. Hybrid Argon Plasma Cut mode will cut and coagulate the tissue at the same time. ARGON PLASMA COAGULATION – Argon gas is delivered through the handpiece while the attached electrosurgical generator is set in the COAG mode. Argon Plasma Coagulation will coagulate the tissue. The Canady Vieira Hybrid Plasma™ Scalpel is an accessory that is used with the Argon 2 (CPC2) and Argon 4 (CPC4) generators, previously cleared by FDA. These generators provide a controlled flow of argon to the electrosurgical handpiece during Hybrid Plasma Cutting or Argon Plasma Coagulation modes. The Physician manually sets the flow rate on the Plasma coagulator. The telescoping nozzle can be extended or shortened over the electrode as desired when the surgeon is performing argon procedures.

5. Indications for Use (IFU)

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

6. Summary of Performance Data

Biocompatibility Testing

Biocompatibility testing was performed to validate the patient contacting material used for the Canady Vieira Hybrid Plasma™ Scalpel. These tests were conducted to meet ISO 10993-1 and USP requirements.

Performance Testing – Bench Studies

Testing was completed to ensure that the Canady Vieira Plasma ™ Scalpel meets the requirements of IEC 60601-1-2 and IEC 60601-2-2 and to ensure that it is compatible with the Canady Plasma Argon 2 and Argon 4 Electrosurgical Generators SS-200-E and SS-601-MCa. Bench Testing was also performed to ensure cutting and coagulation using the device, as well as shelf life and sterility testing.

Performance Testing – Clinical Studies

No Clinical studies were performed for the submission of this 510(k).

7. Safety & Effectiveness

Trade Name	Canady Vieira Hybrid Plasma Scalpel	Telescoping PenEvac ABC	Force Argon II Enhanced Electrosurgical System	Significant Difference
Manufacturer	USMI	I.C. Medical, Inc.	ValleyLab,	N/A
510(k) Number	TBD	K955020	K964636	N/A
Model	422552	N/A	E2520H	N/A
Indications for Use	Hybrid Plasma provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used.	Electrosurgery cut and coagulation / Argon Plasma Coagulation during open surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used.	Argon Shrouded Cut/ Argon Enhanced Coagulation Electrosurgery cut and coagulation used in open, surgical procedures where monopolar electrosurgery (cutting, coagulation) is normally used	None
Handpiece, Telescoping tip	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
Disposable	Yes	Yes	Yes	None
Reusable	No	Yes	No	None
Sterilization Method	EO	EO	EO	None
Needle tip length	2.5cm	2.5cm	2.5cm	None
Buttons on scalpel	3 buttons	3 buttons	3 buttons	None
Gas Flow Rate as Defined	0.1 to 10.0 l/min	0.5 to 12.0 l/min	0.5 to 12.0lmin	None
Bipolar/Monopolar	Monopolar	Monopolar	Monopolar	None
Meets IEC 60601-1-2	Yes	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	Yes	None
Probe Tip	Ceramic	CERAMIC	Ceramic	None
Electrode material	Tungsten	TUNGSTEN	Tungsten	None
Instrument Recognition	Yes	Yes	Yes	None
Meets Biocompatibility	Yes	Yes	Yes	None

As demonstrated in the above table the Canady Vieira Hybrid Plasma™ Scalpel is substantially equivalent to the predicate devices listed in this 510(k) submission. The Canady Vieira Hybrid Plasma ™ Scalpel compared to the predicate devices does not raise issues with regards to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

U.S. Medical Innovations, LLC
% TÜV SÜD America, Inc.
Mr. Alexander Schapovalov
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K113500
Trade/Device Name: Canady Vieira Hybrid Plasma™ Scalpel
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 22, 2011
Received: November 25, 2011

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Canady Vieira Hybrid Plasma™ Scalpel

Indications for Use:

The Hybrid Plasma Scalpel provides cutting and gas coagulation during open surgical procedure where monopolar electrosurgery (cutting and coagulation) is normally used. The Hybrid Plasma Scalpel is a monopolar handpiece used with compatible electrosurgical units.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113500